

Clinical Laboratory Program99 Chauncy Street, 2nd Floor, Boston, MA 02111

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BLOOD COLLECTION STATIONS / PATIENT SERVICE CENTERS**FACT SHEET**

The regulations relating to Blood Collection Stations can be found in the “Rules and Regulations Relating to the Operation, Approval and Licensing of Clinical Laboratories (105 CMR 180.000)”.

DEFINITION

A facility where materials or specimens are either withdrawn or collected from patients or assembled after being withdrawn or collected elsewhere from patients for subsequent delivery to a clinical laboratory for examination. A collection station is a facility which is maintained at a separate physical location, not on the grounds or premises of the main licensed laboratory or institution which performs the testing.

WHO CAN HAVE A BLOOD COLLECTION STATION

A clinical laboratory licensed by the Commonwealth of Massachusetts

A hospital or clinic licensed by the Commonwealth of Massachusetts

Out-of-state laboratories accredited or licensed in accordance with Federal law

WHAT ACTIVITIES MAY BE PERFORMED AT A BLOOD COLLECTION STATION

Collection of specimens

Processing of specimens [centrifugation, planting, incubation]

NO LABORATORY TESTING MAY BE PERFORMED**WHO IS RESPONSIBLE FOR THE BLOOD COLLECTION STATION**

The director of the laboratory of which the approved Blood Collection Station is a part shall be responsible for all aspects of the Blood Collection Station, including without limitation:

- the physical plant
- personnel
- processing and transport of specimens.

The director of the laboratory of which the approved blood collection station is a part (or his/her designee) shall:

1. be available to Blood Collection Station personnel at all times during the operation of the station for personal or telephone consultation;
2. make periodic personal inspections of the station to insure suitable handling of patients and specimens and to instruct the employees in such matters and in the most recent improvements in technique;
3. establish protocol for action in cases of emergency which must include, without limitation, the immediate availability of a physician or emergency medical services.

WHAT IS THE PROCEDURE FOR OPENING A BLOOD COLLECTION STATION

Any permanent area other than the actual laboratory facility which is used for the collection of specimens shall be inspected **PRIOR** to use.

The Department shall issue a certificate / letter of approval once it has ascertained that the Blood Collection Station is in compliance with all applicable regulations.

Correspondence requesting approval for the opening of a Blood Collection Station should be sent to:

**Clinical Laboratory Program
99 Chauncy Street, 2nd Floor
Boston, MA 02111**

Include address of Blood Collection Station, phone number, hours of operation, contact person, tentative opening date

The Notification Form for Blood Collection Stations may be used

WHAT IS THE PROCEDURE FOR CLOSING A BLOOD COLLECTION STATION

The licensee or director of a laboratory shall notify the Department in writing immediately when the operations of an approved Blood Collection Station are about to terminate.

Written correspondence should be sent to address noted above.

Include the location where the records will be stored, the person who will be responsible for the records and the effective closure date

The Notification Form for Blood Collection Stations may be used

WHAT IS THE PROCEDURE FOR RELOCATING A BLOOD COLLECTION STATION

Notify the Department at the address noted above.

Include the old location of the Blood Collection Station, the new address and phone number, the contact person, and the tentative opening date for the new location.

The new location needs to be approved by the Department **PRIOR** to providing services

The Notification Form for Blood Collection Stations may be used

PERTINENT REGULATIONS / HIGHLIGHTS

An approved Blood Collection Station shall meet all applicable requirements set forth in Conditions 105 CMR 180.250 (Management) and 105 CMR 180.040 (General).

An approved Blood Collection Station shall meet all applicable requirements set forth in 105 CMR 480.000 [Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste].

An approved Blood Collection Station shall comply with all federal, state and local laws.

An approved Blood Collection Station shall be identified by signs and advertising in a manner which does not suggest that the station is a laboratory.

No laboratory examinations shall be performed in a Blood Collection Station other than the separation of plasma and serum and such other preparative procedures as the Department may allow.

Any technical employee of a Blood Collection Station must be proficient in venipuncture, specimen processing as limited by the regulations, and emergency procedures required to aid a distressed patient.

A Blood Collection Station shall possess at a minimum:

- blood drawing chair or cot acceptable to the Department;
- telephone (appropriately located);
- adequate hand washing and toilet facilities for employees and patients within the station;
- written procedure manual detailing the steps to be followed in the event of a medical emergency.

OCCUPANCY PERMIT

The occupancy permit for the building in which the Blood Collection Station is located must be current.

WASTE DISPOSAL

The “contaminated” waste generated at the Blood Collection Station is the responsibility of the laboratory of which the Blood Collection Station is a part. A manifest must be completed by the Blood Collection Station and the appropriate signed copies must be filed on-site.